

## **REMARKS**

Claims 1-20 are pending in the case, of which claims 1, 12 and 17 are independent claims. No claims have been amended.

### **Claim Rejections**

Claims 1-20 stand rejected under 35 U.S.C. §103(a) as obvious in view of U.S. Patent No. 6,645,177 (“Shearn”). In addition, claims 1, 12, and 17 stand rejected under 35 U.S.C. § 103(a) as obvious in view of U.S. Published Application No. 2002/0045861 (“Tribe”). Applicants respectfully traverse all of these rejections because neither Shearn nor Tribe teach or suggest a device, apparatus, or method that may determine the displacement of a plunger rod from a fiducial reference position.

### **Claims 1-11**

Claim 1 is directed to a displacement sensor for a substance dispensing device that includes, *inter alia*, a processor for determining a displacement of a plunger rod relative to a fiducial reference position.

The Office Action asserts that Shearn “discloses a processor to determine position of the plunger at near-end-of-infusion point (as a fiducial reference position) and an end of infusion point (see column 8, lines 20-32).” Applicants respectfully disagree.

Shearn only teaches examining two locations, the near end of infusion position and the end of infusion position. The system does not teach determining the location of the displacement of a plunger rod from the near-end-of-infusion point (if such a point may even be called a fiducial reference position). Rather, the system of Shearn determines when the plunger reaches the end-of-infusion point when it detects no dark and light signals (Col. 8, lines 23-32). This determination is not based on the distance from the near-end-of- infusion point.

Indeed, the Office Action explicitly states that Shearn does not disclose determining the displacement of a plunger relative to a fiducial reference position but asserts that “such would have been obvious to one of ordinary skill in the art as it would allow for accurate determination of positioning and accurate determination of the liquid volume in the syringe.” Applicants respectfully disagree.

In order to make a *prima facia case* of obviousness, the Office Action must show that there is a motivation to make the proposed modification. Here, that requirement is not met. Indeed, MPEP §2143.01 explicitly states that “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” That same section also explicitly states that “Although a prior art device ‘may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.”(emphasis added) Here, the motivation does not come from the reference. Rather, the Office Action, without any mention of where a motivation to modify Shearn might come from, asserts that one of ordinary skill in the art would make the proposed modification on their own accord. This flies in the face of the teachings of Shearn which only determines two positions to ensure that an alarm is generated when, or soon before, a plunger reaches an end of infusion location. The goal of Shearn is to determine when a syringe needs to be replaced. Shearn performs this task admirably, so well indeed that one would not be motivated to modify it.

Accordingly, the Office Action has failed to make a *prima facie case* obviousness over Shearn because one of ordinary skill would not be motivated to make the proposed modification. As such, Applicants respectfully assert that claim 1 is patentable over Shearn.

The teachings of Tribe similarly do not render claim 1 obvious. Indeed, the teaching of Tribe are limited to monitoring pulses as a plunger turns and generating an alarm when the pulse rate falls below a specific threshold thus indicating a blockage in the syringe. There is however, no teaching or suggestion of determining position at all in Tribe. As such, claim 1 is patentable over Tribe.

Claims 2-10 depend from claim 1 and, therefore, are patentable for at least the same reasons.

### **Claims 12-16**

Claim 12 is directed to a dispensing apparatus that includes, *inter alia*, a processor for determining a displacement of a plunger rod relative to a fiducial reference position. As discussed above, neither Shearn nor Tribe teach or suggest an apparatus that includes a processor for determining a displacement of a plunger rod relative to a fiducial reference position. Claim 12, therefore, is patentable over Shearn and Tribe.

Claims 13-16 depend from claim 12 and, therefore, are patentable for at least the same reason.

### **Claims 17-20**

Claim 17 is directed to a method for measuring a rate of dispensing a substance by means of dispenser having a piston that includes, *inter alia*, a step of determining a displacement of a plunger rod relative to a fiducial reference position. As discusses above, neither Shearn nor Tribe teach or suggest a method that includes a step of determining a displacement of a plunger rod relative to a fiducial reference position. Claim 17, therefore, is patentable over Shearn and Tribe.

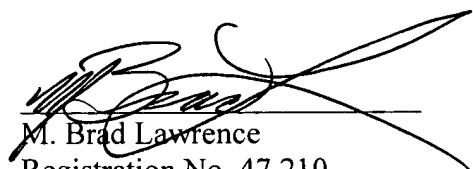
Claims 18-20 depend from claim 17 and, therefore, are patentable for at least the same reasons.

### **Conclusion**

Applicants respectfully request that the examiner reconsider this application in view of all of the art. Applicants submit that the present application is in condition for allowance and early notice to that effect is respectfully solicited.

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Respectfully submitted,



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